

Mesalamine for Colorectal Cancer Prevention Program in Lynch syndrome

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This is a multicenter, multinational, randomized, 2-arm, double-blind, phase II clinical study with 2000mg mesalamine (5-ASA) or placebo in LS patients for a 2-year treatment. 260 tumor free carriers of a known genetic mutation in a major MMR gene (including patients in which the polyps are endoscopically removed) will be randomized 1:1 to receive 2000mg mesalamine or placebo. Patients will be identified through local or national registries and through collaboration with sites. Tumor free patients, assessed by white light high resolution colonoscopy, will be randomized to the study. Blood and stool samples will be collected for analysis of microbiota, ctDNA and potential biomarkers. Biopsies of the normal tissue of ascending colon and rectum will be taken at the first and the last colonoscopy.

The aim of the study is to investigate the effect of regular treatment with mesalamine (5-ASA) on the occurrence of any colorectal neoplasia, tumor multiplicity (the number of detected adenomas/carcinomas) and tumor progression in LS patients.

Tumor multiplicity and tumor progression (severity of the neoplastic lesions) will be investigated.

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